REMARKS

I. Introduction

The Office Action mailed February 27, 2009, has been carefully considered. The present Amendment is intended to be a complete response thereto and to place the case in condition for allowance.

II. Status of the Claims

Claims 1-27, 29-39, and 45-121 are pending. Claims 28 and 40-44 have been cancelled. Claims 1-22, 30, 32, 33, 46-116, and 121 have been withdrawn from consideration by the Examiner as being drawn to non-elective invention or species. Claim 23 has been amended. Support for the amendment is found, *inter alia*, in the specification on page 21, line 9, to page 22, lines 3; and Figure 6.

III. Summary of the Office Action

In the office action, the Examiner rejected

1) claims 23-29, 31, 34-39, and 117-118 under 35 U.S.C. § 103(a) as being obvious over Marchant (U.S. Patent Application Publication No. 2002/0068087) in view of Viegas et al. (U.S. Patent Application Publication No. 2003/0143274), and further in view of Yanni et al. (U.S. Patent No. 6,242,480); and
2) claims 23-27, 29, 31, 34-39, 45, 117 and 118 under 35 U.S.C. § 103(a) as being obvious over Talcott (U.S. Patent No. 4,537,943) in view of Marchant, and further in view of Klopotek (U.S. Patent No. 6,730,123).

IV. Argument

The claims are not obvious for the following reasons:

A. Marchant in view of Viegas et al. and Yanni et al.

Neither Marchant, Viegas et al., nor Yanni et al. disclose every element of the claimed invention. In particular, none of those references discloses the formation of a replacement lens by gelling the reversible hydrogel system in the capsular bag. Marchant discloses bioadhesive hydrogels with degradable crosslink "for use inside the body." *See* paragraph [0021]. "For use inside the body," however, is not the same as formation of a replacement lens in the capsular bag. The invention of Marchant requires making the hydrogel and then using it in the body, not gelating the hydrogel in the body (*in situ* gelation). The applications recited by Marchant do not contemplate *in situ* gelation. For example, the methods recited in paragraphs [0048]-[0050] and in paragraphs [0053]-[0055] recite a step of isolating the crosslinked composition. *In situ* gelation would not allow for the isolation of the crosslinked composition as the gel would already be in the body and its further purification (isolation) is not possible. Therefore, because the gelation of Marchant occurs outside of the body, this reference does not teach *in situ* gellation "to form a lens replacement" as recited in independent claim 23.

The Examiner relies on Viegas et al. to show uses of *in situ* formed gels. However, none of those uses pertains to lens replacement. In paragraphs [0049] and [0051] Viegas et al. disclose the used of the hydrogel as a corneal protective composition. This corneal protective composition presumably involves covering the cornea with the hydrogel; however, this is not the same as *in situ* gellation "to form a lens replacement."

The Examiner relies on Yanni et al. to disclose injection of viscoelastic material into "the anterior chamber and capsular bag." Office Action, page 4. Specifically, Yanni et al. discloses

the use of the viscoelastic material to "prevent collapse of the anterior chamber and to protect tissue from damage resulting from physical manipulation." Column 2, lines 28-32. Additionally, the reference also suggests the use of the viscoelastic composition to "aid in the amelioration of inflammation, tissue damage and trauma-induced complication resulting from anterior segment surgery." Column 2, lines 34-38. However, Yanni et al. do not disclose or contemplate using the viscoelastic material to form a lens replacement. That is because Yanni et al. already use an intraocular lens (IOL) to replace the original lens. This method is discussed in detail in the present specification on pages 2-3 and is not desired by the present invention. The combination of Marchant, Viegas et al., and Yanni et al. does not result in *in situ* gellation "to form a lens replacement." At best, the combination suggests the use a hydrogel system to "prevent collapse of the anterior chamber and to protect tissue from damage resulting from physical manipulation" or to "aid in the amelioration of inflammation, tissue damage and trauma-induced complication resulting from anterior segment surgery," as disclosed by Yanni et al. Therefore, because the combination of Marchant, Viegas et al., and Yanni et al. does not disclose every element of the present invention, those references cannot render the present obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicant respectfully requests withdrawal of the rejection.

With regard to the footnote on page 4 of the Office Action, the Examiner states as follows:

> The Examiner notes that physiological environments have pH values ranging from 6.5 to 7.5. Therefore when the compositions are injected into the body, the limitations of claim 29 are met.

Applicant respectfully submits that this assertion is erroneous. Claim 29 recites that the "oxidization occurs at a pH of about 6.5 to about 7.5." When the solution is introduced into the capsular bag, its pH does not automatically takes on physiological pH. The capsular bag is, at

this stage, an empty sac; and there is no physiological means for the body to the control or regulate the pH inside the sac. As such, when the solution is injected into the capsular bag, the pH of the solution is the same pH as when the solution is outside the body. Moreover, physiological pH is generally used to indicate blood pH. The Examiner has mistaken this to be the pH everywhere in the body, which is not true. Localization of pH variation in the body is possible. Not everything that is injected into the body takes on a pH between 6.5 to 7.5.

B. Talcott in view of Marchant and Klopotek

The Examiner alleges that it would have been obvious to use the hydrogel of Marchant in the lens of Talcott. Specifically, the Examiner alleges that "it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use." Office Action, page 6. Applicant respectfully submits that the material of Marchant is not suitable for use in the lens of Talcott. Talcott discloses an *in vivo* lens to be used as a replacement for a defective natural lens. Marchant discloses a degradable hydrogel. This is not compatible with the lens of Talcott that is used a natural lens replacement. Specifically, Marchant states as follows:

> This invention will result in new formulation and application opportunities where degradable crosslinking schemes are beneficial such as controlled release formulations for pharmaceutical or agricultural application. This release may be achieved through both diffusion and degradative processes in the gel.

Page 5, paragraph [0068].

> To ensure eventual clearance from the body, the hydrogel is made up of polymeric backbones of molecular weight below renal clearance (45 kD) crosslinked by degradable links.

Page 5, paragraph [0075]. Thus, the hydrogel of Marchant is designed to be degradable and

eventually removed from the body. This degradable gel clearly is not desirable for use as a lens replacement, as it is not desirable to have a patient go through painful surgery to replace a lens, only to have the new lens degrade. The material of Marchant is thus clearly not suitable for use with the lens of Talcott.

With regard to Klopotek, that reference discloses an IOL with an optical chamber deformable under influence of a fluid. The fluid can thus be used to change the focusing performance of the IOL. The Examiner alleges that this reference teaches the "benefits of have [*sic*] an adjustable implanted intraocular lens." Office Action, page 6. Applicant respectfully submits that the IOL of Klopotek is the kind of lens that Talcott tries to avoid. Focusing performance of the IOL of Klopotek can be changed using the associated fluid. The lens of Talcott is not adjustable by any external fluid. It mimics the natural lens, and thus, can be focused using the cilliary muscles. That is impossible with the IOL of Klopotek. As such, Klopotek uses external fluid to focus his lens. Klopotek also does not cure the deficiency of Marchant.

Therefore, for the reasons noted, the present invention is not obvious over the combination of Talcott, Marchant, and Klopotek. Accordingly, Applicant respectfully requests withdrawal of the rejection.

V. Conclusion

Applicant has responded to the Office Action mailed February 27, 2009. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney

concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (111828.0110). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, Applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time for as many months as are required to render this submission timely.

Any fees due are authorized above.

Respectfully submitted,

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